

Applicant: Fitzhugh et al. Serial No.: 10/623239 Filed: July 17, 2003

Title: Highly Cross-Linked,

Extremely Hydrophobic Nitric Oxide-Releasting Polymers & Methods for Their Manufacture & Use

Group Art Unit: Unassigned Examiner: Unassigned

Docket No.: 14364.99

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Commissioner for Patents Mail Stop DD P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

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A Patent and Trademark Office Form 1449 listing each of these informational items is enclosed along with a copy of each item. A copy of the cited references are not included. Copies can be found in the parent case, U.S. application serial number 09/972219 filed October 4, 2001.

This Information Disclosure Statement is being filed before the mailing date of the first Office Action issued on the merits of the subject application in accordance with 37 C.F.R. §1.97(b)(3). In the event that a first Office Action has been mailed to the undersigned prior to the mailing of this Information Disclosure Statement, the Commissioner is hereby authorized to charge payment of the applicable fee pursuant to 37 C.F.R. § 1.17(p) to Deposit Account No. 50-1329. A duplicate copy of this document is enclosed.

Respectfully submitted,

September 2, 2003

Louis C. Cullman Registration No. 39,645

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j	1	SEP 0 4 2003		Application Number	09/972,219
		DISCLOSUK		Filing Date	10/04/2001
ST	ATEMENT B	YMPPHISAN.	Γ	First Named Inventor	Fitzhugh et al.
				Group Art Unit	1616
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Sheet	1	of	3	Attorney Docket Number	17363-20

				U.S. PATENT DOCUME	NTS	
Examiner Initials	Cite No.1	U.S. Patent Number	Document Kind Code ²	Date of Publications of Cited Documents MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		4954526	1	09/04/1990	Keefer	
		5039705		08/13/1991	Keefer et al.	
		5155137		10/13/1992	Keefer et al.	
		5171217	<u> </u>	12/15/1992	March et al.	
		5212204	1	05/18/1993	Keefer et al.	
		5229172		07/20/1993	Cahalan et al.	
•		5250550		10/05/1993	Keefer et al.	
		5268465	<u> </u>	12/07/1993	Bredt et al.	
		5366997	 	11/22/1994	Keefer et al.	
		5380758		01/10/1995	Stamler et al.	
		5405919		04/11/1995	Keefer et al.	
		5428070	<u> </u>	06/27/1995	Cooke et al.	
		5468630	1	11/21/1995	Billiar et al.	
· · · · · · · · · · · · · · · · · · ·		5482925		01/09/1996	Hutsell	
		5519020		05/21/1996	Smith et al.	
		5525357		06/11/1996	Keefer et al.	-
		5574068		11/12/1996	Stamler et al.	
		5583101		12/10/1996	Stamler et al.	
	 	5632981		05/27/1997	Saavedra et al.	
		5650447		07/22/1997	Keefer et al.	
***		5658565		08/19/1997	Billiar et al.	
		5676963		10/14/1997	Keefer et al.	
		5683668		11/04/1997	Hrabie et al.	
		5691423		11/25/1997	Smith et al.	
	1	5700830		12/23/1997	Korthuis et al.	
		5714511		02/03/1998	Saavedra et al.	
		5718892		02/17/1998	Keefer et al.	
		5721365		02/24/1998	Keefer et al.	
	 	5770645		06/23/1998	Stamler et al.	
		5789447	1	08/04/1998	Wink, Jr. et al.	
		5814656	 	09/29/1998	Saavedra et al.	
		5814667		09/29/1998	Mitchell et al.	
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ن		12		Application Number	09/972,219
IN	IFORMATION	DISCLOSUF	367	Filing Date	10/04/2001
S	TATEMENT E	Y APPEICA	Y	First Named Inventor	Fitzhugh et al.
				Group Art Unit	1616
	(use as many she	ets as necessary)	1	Examiner Name	Unassigned
Sheet	2	of	3	Attorney Docket Number	17363-20

	5837313	11/17/1998	Ding et al.	
	5837736	11/17/1998	Mitchell et al.	
	5840759	11/24/1998	Mitchell et al.	
	5877216	03/02/1999	Place et al.	
	5891459	04/06/1999	Cooke et al.	
	5910316	06/08/1999	Keefer et al.	
	5945452	08/31/1999	Cooke et al.	
-	5958427	09/28/1999	Salzman et al.	
	5962520	10/05/1999	Smith et al.	
	5994444	11/30/1999	Trescony et al.	
	6024918	02/15/2000	Hendriks et al.	

				FC	DREIGN PATENT DOCUMENTS	3		
		Fore	eign Patent Docu	ment			Pages, Columns, Lines,	76
Examiner Initials	Cite No. ¹	Office ³	Number ⁴	Kind Code	Name of Patentee or Applicant of Cited Document	Date of Publications of Cited Documents MM/DD/YYYY	Where Relevant Passages or Relevant Figures Appear	"
		wo	00/02501		William Harvey Research LTD.	01/20/00		

		OTHER PRIOR ART / NON PATENT LITERATURE DOCUMENTS			
Examiner Initials'	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume/issue number(s), publisher, city and/or country where published.			
	-	Bauer et al.; Evaluation of Linear Polyethyleneimine/nitric Oxide Adduct on Wound Repair: Therapy versus Toxicity; Wound Repair & Regeneration, November/December 1998, pp. 569/577			
	Chandy et al; "Use of Plasma Glow for Surface/Engineering Biomolecules to Enhance Bloodcompatibility of Dacron and PTFE Vascular Prosthesis." Biomaterials 21: 699/712				
	,	Drago; "Free Radicals in Inorganic Chemistry." No. 36, Advances in Chemistry Series, American chemical society, Washington, D. C. 1962, pp. 143/149			
· · · · · · · · · · · · · · · · · · ·		Hanson et al; Nitric Oxide Donors: A Continuing Opportunity in Drug Design; Advances in Pharmacology, Vol 34, pp. 383/398			
	Hrabie et al; "New Nitric Oxide/Releasing Zwitterions Derived from Polyamines." J. Org. Chem. 1993, 1472/1476				
		Jordi; Jordi Gel Columns for Size Exclusion Chromatography; Column Handbook for Size Exclusion Chromatography; 1999, pp. 367/425			
Examine Signature		Date Considered			

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^{&#}x27;Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.)). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent documents. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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	Kaul et al.; Polymeric/Based Perivascular Delivery of a Nitric Oxide Donor Inhibits Intimal Thicening After Balloon Denudation Arterial Injury: Role of Nuclear Factor/kappaB; Journal of the American College of Cardiology, Vol. 35, No. 2, 2000:493/501
	Keefer et al; "NONOates" (1/Substituted Diazen/1/ium/1,2/diolates) as Nitric Oxide Donors: Convenient Nitric Oxide Dosage Forms." Methods in Enzymology, Vol 268: 281/293
	Mowery et al.; Preparation and Characterization of Hydrophobic Polymeric Films That Are Thromboresistant Via Nitric Oxide Release; Biomaterials 21 (2000) 9/21
-	Saavedra et al.; "Conversion of Polysaccharide to Nitric Oxide/Releasing Form Dual/Mechanism Anticoagulant Activity of Diaseniumdiolated Heparin." Bioorganic & Medicinal Chemistry Letters 10 (2000) 1/3
·	Smith et al.; Nitric Oxide/Releasing Polymers Containing the [N(O)NO]' Group; J. Med. Chem. 1996, 39, 1148/1156

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